

c. Costs to private regulated parties: The amendments do not impose any costs on private regulated parties.

d. Cost to the regulatory agency: There are no additional costs to the State Education Department.

5. LOCAL GOVERNMENT MANDATES:

The proposed amendment does not impose any additional program, service, duty or responsibility upon any local government.

6. PAPERWORK:

The proposed amendment does not impose any additional paperwork requirements.

7. DUPLICATION:

The proposed amendment does not duplicate existing State or Federal requirements.

8. ALTERNATIVES:

The proposed amendment is necessary to provide regulatory flexibility in response to the cancellation of the January 2022 Regents examination administration due the COVID-19 crisis so that students can still meet the diploma, credential, and endorsement requirements related to the passing of such examinations. There are no significant alternatives to the proposed amendment and none were considered.

9. FEDERAL STANDARDS:

There are no applicable Federal standards.

10. COMPLIANCE SCHEDULE:

If adopted as an emergency rule at the January 2022 Regents meeting, the proposed amendment will become effective as an emergency rule on January 11, 2022. It is anticipated that the proposed amendment will be presented for permanent adoption at the May 2022 Regents meeting, after publication of the proposed amendment in the State Register and expiration of the 60-day public comment period required under the State Administrative Procedure Act. If adopted at the May 2022 meeting, the proposed amendment will become effective as a permanent rule on June 1, 2022. It is anticipated that regulated parties will be able to comply with the proposed amendment by the effective date.

Regulatory Flexibility Analysis

(a) Small businesses:

The proposed rule provides regulatory flexibility in response to the cancellation of the January 2022 Regents examination administration due the COVID-19 crisis so that students can still meet the diploma, credential, and endorsement requirements related to the passing of such examinations. The proposed amendments do not impose any adverse economic impact, reporting, recordkeeping or any other compliance requirements on small businesses. Because it is evident from the nature of the proposed amendments that they do not affect small businesses, no further measures were needed to ascertain that fact, and none were taken. Accordingly, a regulatory flexibility analysis for small businesses is not required and one has not been prepared.

(b) Local governments:

1. EFFECT OF RULE:

The purpose of the proposed amendments is to provide regulatory flexibility in response to the cancellation of the January 2022 Regents examination administration due the COVID-19 crisis so that students can still meet the diploma, credential, and endorsement requirements related to the passing of such examinations. The proposed amendment applies to all school districts in the State, and to charter schools and nonpublic schools that are authorized to issue regular high school diplomas with respect to State assessments and high school graduation and diploma requirements.

2. COMPLIANCE REQUIREMENTS:

The proposed rule provides exempts students from the diploma, credential, and endorsement requirements related to the January 2022 Regents examinations in response to the cancellation of the January 2022 Regents examination administration due the COVID-19 crisis so that students can still meet the diploma, credential, and endorsement requirements related to the passing of such examinations.

Additionally, the proposed rule permits parents and persons in parental relation to decline the exemption to the graduation assessment requirement(s) for any year that their child has been exempted prior to such child's graduation. Schools must notify parents of the option to decline such exemption to parents and persons in parental relation prior to the conclusion of the semester in which students are due to receive their high school diploma (10 days prior for those graduating after the first semester of the 2021-22 school year and 30 days prior to the second semester of the 2021-22 school year and thereafter).

3. PROFESSIONAL SERVICES:

The proposed amendment does not impose any additional professional services requirements on local governments.

4. COMPLIANCE COSTS:

The proposed amendment will not impose any additional program, service, duty, responsibility or costs on local governments.

5. ECONOMIC AND TECHNOLOGICAL FEASIBILITY:

The proposed rule does not impose any additional costs or technological requirements on local governments.

6. MINIMIZING ADVERSE IMPACT:

The proposed amendments are necessary to provide flexibility in response to the cancellation of the January 2022 Regents examination administration due the COVID-19 crisis so that students can still meet the diploma, credential, and endorsement requirements related to the passing of such examinations. Accordingly, no alternatives were considered.

7. LOCAL GOVERNMENT PARTICIPATION:

Comments on the proposed rule were solicited from school districts through the offices of the district superintendents of each supervisory district in the State and from the chief school officers of the five big city school districts.

Rural Area Flexibility Analysis

1. TYPES AND ESTIMATED NUMBERS OF RURAL AREAS:

The proposed rule applies to all school districts in the State, and to charter schools and nonpublic schools that are authorized to issue regular high school diplomas with respect to State assessments and high school graduation and diploma requirements, including those located in the 44 rural counties with less than 200,000 inhabitants and the 71 towns in urban counties with a population density of 150 per square mile or less.

2. REPORTING, RECORDKEEPING, AND OTHER COMPLIANCE REQUIREMENTS; AND PROFESSIONAL SERVICES:

The proposed rule is necessary to provide regulatory flexibility in response to the cancellation of the January 2022 Regents examination administration due the COVID-19 crisis so that students can still meet the diploma, credential, and endorsement requirements related to the passing of such examinations.

3. COSTS:

The proposed amendment does not impose any additional costs to public, charter and non-public schools, including those in rural areas.

4. MINIMIZING ADVERSE IMPACT:

The proposed rule is necessary provide regulatory flexibility in response to the cancellation of the January 2022 Regents examination administration due the COVID-19 crisis so that students can still meet the diploma, credential, and endorsement requirements related to the passing of such examinations. Therefore, no alternatives were considered for public, charter and non-public schools located in rural areas.

5. RURAL AREA PARTICIPATION:

Comments on the proposed rule will be solicited from school districts through the offices of the district superintendents of each supervisory district in the State, from the chief school officers of the five big city school districts and from charter schools, including those in rural areas.

Job Impact Statement

The proposed rule is necessary to provide regulatory flexibility in response to the cancellation of the January 2022 Regents examination administration due the COVID-19 crisis so that students can still meet the diploma, credential, and endorsement requirements related to the passing of such examinations.

Because it is evident from the nature of the proposed rule that it will have no impact on the number of jobs or employment opportunities in New York State, no further steps were needed to ascertain that fact and none were taken. Accordingly, a job impact statement is not required and one has not been prepared.

EMERGENCY/PROPOSED RULE MAKING NO HEARING(S) SCHEDULED

Administration of Immunizations by Pharmacists

I.D. No. EDU-04-22-00009-EP

Filing No. 20

Filing Date: 2022-01-11

Effective Date: 2022-01-31

PURSUANT TO THE PROVISIONS OF THE State Administrative Procedure Act, NOTICE is hereby given of the following action:

Proposed Action: Amendment of section 63.9 of Title 8 NYCRR.

Statutory authority: Education Law, sections 207, 6504, 6507, 6527, 6801, 6802, 6909; L. 2021, ch. 555

Finding of necessity for emergency rule: Preservation of public health and general welfare.

Specific reasons underlying the finding of necessity: The proposed rule is necessary to implement Chapter 555 of the Laws of 2021 (Chapter 555), which is effective January 31, 2022. This amendment conforms the Commissioner's regulation to Chapter 555, which amends the Education Law, inter alia, to authorize certified pharmacists to administer, pursuant to a

patient-specific order or a non-specific patient order issued by a licensed physician or a certified nurse practitioner, immunizations for: (1) hepatitis A; (2) hepatitis B; (3) human papillomavirus; (4) measles; (5) mumps; (6) rubella; (7) varicella.

Chapter 555 also permits certified pharmacists to administer other immunizations, to patients 18 years old or older, recommended by the Advisory Committee on Immunization Practices (ACIP) of the Centers for Disease Control and Prevention (CDC), if the Commissioner of the Department of Health (DOH) in consultation with the Commissioner determine that an immunization: (1) may be safely administered by a licensed pharmacist within their lawful scope of practice; and (2) is needed to prevent the transmission of a reportable communicable disease that is prevalent in New York State; or (3) is a recommended immunization for such patients who: (a) meet age requirements; (b) lack documentation of such immunization; (c) lack evidence of past infection; or (d) have an additional risk factor or another indication as recommended by the advisory committee on immunization practices of the CDC.

Additionally, Chapter 555 removes the requirement that a licensed physician or certified nurse practitioner, who prescribes or issues a patient specific order or a non-patient specific order for a pharmacist to administer immunizations, must have a practice site in the county or adjoining county in which the immunizations are administered.

Finally, Chapter 555 removes the sunset provisions for the authorization for certified pharmacists to administer certain immunizations.

Since the Board of Regents meets at fixed intervals, the earliest the proposed rule can be presented for adoption, after expiration of the required 60-day public comment period provided for in the State Administrative Procedure Act (SAPA) sections 201(1) and (5), would be the May 16-17, 2022 Regents meeting. Furthermore, pursuant to SAPA section 203(1), the earliest effective date for the proposed rule, if adopted at the May meeting, would be June 1, 2022, the date the Notice of Adoption would be published in the State Register. However, Chapter 555 becomes effective January 31, 2022.

Therefore, emergency action is necessary at the January 2022 meeting for the preservation of the public health and general welfare in order to enable the State Education Department to timely implement the requirements of Chapter 555, which expands the immunizations that certified pharmacists are authorized to administer and the public's access to them.

It is anticipated that the proposed rule will be presented for adoption as a permanent rule at the May 16-17, 2022 Regents meeting, which is the first scheduled meeting after the expiration of the 60-day public comment period prescribed in SAPA for State agency rule makings.

Subject: Administration of Immunizations by Pharmacists.

Purpose: To conform the Commissioner's regulation to chapter 555 of the Laws of 2021 authorizing pharmacists to administer certain immunizations.

Text of emergency/proposed rule: 1. Section 63.9 of the Regulations of the Commissioner of Education is amended, as follows:

Section 63.9. Immunizations and emergency treatment of anaphylaxis pursuant to patient specific and non-patient specific orders and protocols

(a) [Applicability. This section shall apply only to the extent that the applicable provisions in Education Law sections 6527, 6801, 6802, 6828 and 6909, authorizing certified pharmacists to administer certain immunization agents and medications for the emergency treatment of anaphylaxis, have not expired or been repealed.

(b) Immunizations.

(1) Pursuant to section 6801 of the Education Law, a pharmacist with a certificate of administration issued by the department pursuant to paragraph (3) of this subdivision shall be authorized to administer immunization agents prescribed in paragraph (2) of this subdivision to patients therein specified, provided that:

(i) the pharmacist meets the requirements for a certificate of administration prescribed in paragraph (3) of this subdivision and the order and protocol meet the requirements set forth in paragraph (5) of this subdivision; and

(ii) with respect to non-patient specific orders:

(a) the immunization is prescribed or ordered by a *New York State* licensed and registered physician or certified nurse practitioner, with a practice site in [the county or adjoining county in which the immunization is administered] *New York State*; and

(b) if the commissioner of health determines that there is an outbreak of disease, or that there is the imminent threat of an outbreak of disease, then the commissioner of health may issue a non-patient specific regimen applicable statewide.

(2) Authorized immunization agents. A certified pharmacist who meets the requirements of this section shall be authorized to [administer to]:

(i) *administer to* patients 18 years of age or older, immunizing agents to prevent influenza, pneumococcal, acute herpes zoster, *hepatitis*

A, hepatitis B, human papillomavirus, measles, mumps, rubella, varicella, COVID-19, meningococcal, tetanus, diphtheria, [COVID-19,] or pertussis disease, pursuant to a patient specific order or a non-patient specific order; [and]

(ii) *administer to* patients between the ages of two and [eighteen] 18 years of age, immunizing agents to prevent influenza, pursuant to a patient specific order or a non-patient specific order[.]; *and*

(iii) *administer other immunizations recommended by the advisory committee on immunization practices of the centers for disease control and prevention for patients 18 years of age or older, pursuant to a patient specific or a non-patient specific order, if the commissioner of health in consultation with the commissioner determines that an immunization:*

(a) *may be safely administered by a licensed pharmacist within their lawful scope of practice; and*

(b) *is needed to prevent the transmission of a reportable communicable disease that is prevalent in New York State; or*

(c) *is a recommended immunization for such patients who:*

(1) *meet age requirements;*

(2) *lack documentation of such immunization;*

(3) *lack evidence of past infection; or*

(4) *have an additional risk factor or another indication as recommended by the advisory committee on immunization practices of the centers for disease control and prevention.*

[(c)] (b) Anaphylaxis treatment agents.

(1) ...

(2) ...

(3) ...

This notice is intended: to serve as both a notice of emergency adoption and a notice of proposed rule making. The emergency rule will expire April 10, 2022.

Text of rule and any required statements and analyses may be obtained from: Kirti Goswami, NYS Education Department, Office of Counsel, 89 Washington Avenue, Room 112EB, Albany, NY 12234, (518) 474-6400, email: legal@nysed.gov

Data, views or arguments may be submitted to: Sarah S. Benson, Deputy Commissioner, NYS Education Department, Office of the Professions, 89 Washington Ave., 2nd Floor EB, Albany, NY 12234, (518) 474-1431, email: REGCOMMENTS@nysed.gov

Public comment will be received until: 60 days after publication of this notice.

This rule was not under consideration at the time this agency submitted its Regulatory Agenda for publication in the Register.

Regulatory Impact Statement

1. STATUTORY AUTHORITY:

Section 207 of the Education Law grants general rule-making authority to the Board of Regents to carry into effect the laws and policies of the State relating to education.

Section 6504 of the Education Law authorizes the Board of Regents to supervise the admission to and regulation of the practice of the professions.

Paragraph (a) of subdivision (2) of section 6507 of the Education Law authorizes the Commissioner of Education to promulgate regulations in administering the admission to and the practice of the professions.

Subdivision (7) of section 6527 of the Education Law, as amended by Chapter 555 of the Laws of 2021, authorizes physicians to prescribe and order a patient specific order or non-patient specific regimen to a certified pharmacist¹ for: (a) administering immunizations to prevent influenza to patients two years of age or older; and (b) administering immunizations to prevent pneumococcal, acute herpes zoster, hepatitis A, hepatitis B, human papillomavirus, measles, mumps, rubella, varicella, COVID-19, meningococcal, tetanus, diphtheria, COVID-19, or pertussis disease and medications required for emergency treatment of anaphylaxis to patients eighteen years of age or older; and (c) administering other immunizations recommended by the Advisory Committee on Immunization Practices (ACIP) of the Centers for Disease Control (CDC) and prevention for patients eighteen years of age or older if the Commissioner of the New York State Department of Health (DOH) in consultation with the Commissioner of the New York State Education Department (SED) determines that an immunization meets certain specified requirements.

Section 6801 of the Education Law defines the practice of the profession of pharmacy and establishes various requirements relating to the administration of immunizations by licensed pharmacists, including, inter alia, the training requirements licensed pharmacists must satisfy to become certified to administer immunizations, reporting requirements for all vaccines administered by certified pharmacists and requirements regarding the provision of information by the certified pharmacist, regarding the immunization, to either the patient or the person legally responsible for the patient, as well as the requirement that a certified pharmacist, when administering an immunization in a pharmacy, provide for an area that provides for the patient's privacy.

Paragraphs (a) and (b) of subdivision (22) of section 6802 of the Education Law, as amended by Chapter 555 of the Laws of 2021, defines the terms administer and immunizing agent and authorizes licensed pharmacists to execute patient specific and non-patient specific orders prescribed by a licensed physician or certified nurse practitioner for: immunizations to prevent influenza, pneumococcal, acute herpes zoster, hepatitis A, hepatitis B, human papillomavirus, measles, mumps, rubella, varicella, COVID-19, meningococcal, tetanus, diphtheria, COVID-19, or pertussis disease and medications required for emergency treatment of anaphylaxis; and other immunizations recommended by the ACIP of the CDC for patients eighteen years of age or older if the Commissioner of DOH in consultation with the Commissioner of SED determines that an immunization meets certain specified requirements.

Paragraphs (a) and (b) of subdivision (22) of section 6802 of the Education Law, as amended by Chapter 555 of the Laws of 2021, also removes the requirement that a licensed physician or certified nurse practitioner, who prescribes or issues a patient specific order or a non-patient specific order for a pharmacist to administer immunizations, must have a practice site in the county or adjoining county in which the immunizations are administered.

Subdivision (7) of section 6909 of the Education Law, as amended by Chapter 555 of the Laws of 2021, authorizes nurse practitioners to prescribe and order a patient specific order or non-patient specific regimen to a licensed pharmacist for: (a) administering immunizations to prevent influenza, to patients two years of age or older; and (b) administering immunizations to prevent pneumococcal, acute herpes zoster, hepatitis A, hepatitis B, human papillomavirus, measles, mumps, rubella, varicella, COVID-19, meningococcal, tetanus, diphtheria, COVID-19, or pertussis disease and medications required for emergency treatment of anaphylaxis to patients eighteen years of age or older; and (c) administering other immunizations recommended by the ACIP of the CDC for patients eighteen years of age or older if the Commissioner of DOH in consultation with the Commissioner of SED determines that an immunization meets certain specified requirements.

2. LEGISLATIVE OBJECTIVES:

The proposed rule implements Chapter 555 of the Laws of 2021 (Chapter 555), which effective January 31, 2022, inter alia, amends the Education Law to authorize certified pharmacists to administer, pursuant to a patient-specific order or a non-specific patient order issued by a licensed physician or a certified nurse practitioner, immunizations for: (1) hepatitis A; (2) hepatitis B; (3) human papillomavirus; (4) measles; (5) mumps; (6) rubella; and (7) varicella.

Chapter 555 also permits certified pharmacists to administer other immunizations, to patients 18 years old or older, recommended by the ACIP of the CDC. This is conditioned on a determination by the Commissioner of DOH, in consultation with the Commissioner of SED, that an immunization: (1) may be safely administered by a licensed pharmacist within their lawful scope of practice; and (2) is needed to prevent the transmission of a reportable communicable disease that is prevalent in New York State; or (3) is a recommended immunization for such patients who: (a) meet age requirements; (b) lack documentation of such immunization; (c) lack evidence of past infection; or (d) have an additional risk factor or another indication as recommended by the ACIP of the CDC.

This law also removes the requirement that a licensed physician or certified nurse practitioner, who prescribes or issues a patient specific order or a non-patient specific order for a pharmacist to administer immunizations, must have a practice site in the county or adjoining county in which the immunizations are administered.

Finally, it eliminates the sunset provisions for the authorization for certified pharmacists to administer certain immunizations, making such provisions permanent.

The proposed rule amends section 63.9 of the Commissioner's regulations to implement the provisions of Chapter 555 as follows:

- Subdivision (a) of such section is amended to remove the sunset provisions for the authorization for certified pharmacists to administer certain immunizations;
 - Clause (b)(1)(ii)(a) of such section is amended to remove the requirement that the licensed physician or certified nurse practitioner who prescribes or issues a patient specific order or a non-patient specific order (for a pharmacist to administer immunizations) must have a practice site in the county or adjoining county in which the immunizations are administered. It also clarifies that the physician or certified nurse practitioner who issues such orders must be licensed, registered, and maintain a practice site in New York State;
 - Subparagraph (b)(2)(i) of such section is amended to add hepatitis A, hepatitis B, human papillomavirus, measles, mumps, rubella, and varicella to the list of immunizing agents that certified pharmacists can administer to patients 18 years of age or older, pursuant to a patient specific or a non-patient specific order; and
 - A new subparagraph (b)(2)(iii) is added to permit certified pharmacists

to administer other immunizations recommended by the ACIP for patients eighteen years of age or older, pursuant to a patient specific or a non-patient specific order, if the Commissioner of DOH in consultation with the Commissioner determines that an immunization:

- (1) may be safely administered by a licensed pharmacist within their lawful scope of practice; and
- (2) is needed to prevent the transmission of a reportable communicable disease that is prevalent in New York State; or is a recommended immunization for such patients who:
 - (a) meet age requirements;
 - (b) lack documentation of such immunization;
 - (c) lack evidence of past infection; or
 - (d) have an additional risk factor or another indication as recommended by the ACIP of the CDC.

3. NEEDS AND BENEFITS:

The purpose of the proposed rule is to make immunizations more readily available to the public by authorizing certified pharmacists, pursuant to patient specific and non-patient specific orders issued by a licensed physician or certified nurse practitioner, to administer more types of immunizations. The proposed rule is necessary to conform the Commissioner's regulations to Chapter 555.

4. COSTS:

- (a) Costs to State government: There are no additional costs to state government.
- (b) Costs to local government: There are no additional costs to local government.
- (c) Cost to private regulated parties. There are no mandatory costs to private regulated parties.
- (d) Cost to the regulatory agency: There are no additional costs to the Department.

5. LOCAL GOVERNMENT MANDATES:

The proposed rule does not impose any program service, duty, responsibility, or other mandate on local governments.

6. PAPERWORK:

The proposed rule does not impose any paperwork mandates because it does not require pharmacists to become certified to administer immunizations. For pharmacists, who choose to become certified to administer immunizations, they would be responsible for complying with any of the reporting, recordkeeping or other requirements that certified licensed pharmacists must comply with when immunizing people.

7. DUPLICATION:

There are no other state or federal requirements on the subject matter of the proposed rule. Therefore, the amendment does not duplicate other existing state or federal requirements.

8. ALTERNATIVES:

The proposed rule implements statutory requirements. There are no significant alternatives to the proposed rule and none were considered.

9. FEDERAL STANDARDS:

Since there are no applicable federal standards, the proposed rule does not exceed any minimum federal standards for the same or similar subject areas.

10. COMPLIANCE SCHEDULE:

The proposed rule is necessary to conform the Commissioner's regulations to Chapter 555, which, among other things, expands the types of immunizations that certified pharmacists can administer, pursuant to patient specific and non-patient specific orders issued by license physicians or certified nurse practitioners. If adopted at the May 2022 Regents meeting, the proposed amendment to section 63.9, of the Commissioner's regulations will become effective on June 1, 2022. It is anticipated that the regulated parties will be able to comply with the proposed rule by the effective date.

¹In order to administer authorized immunizations, a licensed and registered pharmacist must be certified by the Department following the completion of a satisfactory training program.

Regulatory Flexibility Analysis

The purpose of the proposed rule is to implement Chapter 555 of the Laws of 2021 (Chapter 555), which effective January 31, 2022, inter alia, amends the Education Law to authorize certified pharmacists¹ to administer, pursuant to a patient-specific order or a non-specific patient order issued by a licensed physician or a certified nurse practitioner, immunizations for: (1) hepatitis A; (2) hepatitis B; (3) human papillomavirus; (4) measles; (5) mumps; (6) rubella; and (7) varicella. Chapter 555 enacted to make additional immunizations more readily available to the public.

Chapter 555 also permits certified pharmacists to administer other immunizations, to patients 18 years old or older, recommended by the ACIP of the CDC. This is conditioned on a determination by the Commissioner of DOH, in consultation with the Commissioner of SED, that an immunization: (1) may be safely administered by a licensed pharmacist within their lawful scope of practice; and (2) is needed to prevent the transmission of a reportable communicable disease that is prevalent in